UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

JUN 13 1997

**MEMORANDUM**

**SUBJECT:** Raid BD493: Review of Acute Toxicity Data Submitted by the Registrant.

**EPA Identification Numbers:**

DP Barcode: D235923 Submission: S520836
MRID#'s: 44186004 through 44186008; 44218901.
P.C. Code: 069104

**TO:** Walter Francis
PM Team # 31
Antimicrobial Division (7505W)

**FROM:** Timothy F. McMahon, Ph.D. 6/11/97
Pharmacologist, RASSB
Antimicrobial Division (7505W)

**THRU:** Norm Cook 06.13.97
Chief, RASSB
Antimicrobial Division

**Registrant:** S.C. Johnson & Son, Inc.

**Action Requested:** Review of acute toxicity studies submitted for Raid BD493, a quaternary ammonium formulation, under a "me-too" application.

**Data Summary**

**1) Acute Oral Toxicity in Rats, MRID # 44186004**

Citation: Glaza, Steven M. (1993): Acute Oral Toxicity of Raid BD493 /n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) Dimethyl Benzyl Ammonium Chloride/n-Alkyl (68% C12, 32% C14) Dimethyl Ethylbenzyl Ammonium Chloride/3-(trimethoxysilyl) Propyl Dimethyl Octadecyl Ammonium Chloride [7217H121] in Rats. Hazleton Wisconsin, Inc. Laboratory Project I.D. HWI 21103437. MRID # 44186004. Unpublished.

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID # 44186004), young adult Crl:CD®BR strain rats (5/sex), were given a single oral dose of 5,000 mg/kg Raid BD493 and observed for clinical toxicity and mortality for up to 14 days post-dose.

**Estimated Oral $LD_{50}$ Males > 5,000 mg/kg**
**Estimated Oral $LD_{50}$ Females > 5,000 mg/kg**

Raid BD493 is assigned TOXICITY CATEGORY IV based on the LD50 in males and females.

This acute oral toxicity study is classified **acceptable** and satisfies the guideline requirement (§81-1) for an acute oral toxicity study.

**2) Acute Dermal Toxicity in Rabbits, MRID # 44186005**

CITATION: Glaza, Steven M. (1993): Acute Dermal Toxicity of Raid BD493 /n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) Dimethyl Benzyl Ammonium Chloride/n-Alkyl (68% C12, 32% C14) Dimethyl Ethylbenzyl Ammonium Chloride/3-(trimethoxysilyl) Propyl Dimethyl Octadecyl Ammonium Chloride [7217H121] in Rabbits. Hazleton Wisconsin, Inc. Laboratory Project I.D. HWI 21103438. MRID # 44186005. Unpublished.

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID # 44186005), young adult Hra:(NZW)SPF strain rabbits (5/sex), were given a single dermal application of 2,000 mg/kg Raid BD493 and observed for clinical toxicity and mortality for up to 14 days post-dose.

**Estimated Dermal $LD_{50}$ Males > 2,000 mg/kg**
**Estimated Dermal $LD_{50}$ Females > 2,000 mg/kg**

Raid BD493 is assigned TOXICITY CATEGORY III based on the LD50 in males and females.

This acute dermal toxicity study is classified **acceptable** and satisfies the guideline requirement (§81-2) for an acute dermal toxicity study.

### 3) Acute Inhalation Toxicity in Rats, MRID # 44218901

CITATION: Hoffman, Gary M. (1993): An Acute (4-Hour) Inhalation Toxicity Study of Raid BD493 /n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) Dimethyl Benzyl Ammonium Chloride/n-Alkyl (68% C12, 32% C14) Dimethyl Ethylbenzyl Ammonium Chloride/3-(trimethoxysilyl) Propyl Dimethyl Octadecyl Ammonium Chloride [7217H121] in the Rat via Nose-Only Exposure. Huntingdon Life Sciences, East Millstone, New Jersey. Study No. 92-5125 MRID # 44218901. Unpublished.

EXECUTIVE SUMMARY: In an acute (4-hour) inhalation toxicity test, male and female rats of the Sprague-Dawley strain (approximately 2 months old) were exposed nose-only to Raid BD493 at analytical concentrations of 4.8 and 5.6 mg/l as a liquid aerosol. Rats were observed for signs of clinical toxicity and mortality for up to 15 days post-exposure.

**Estimated Inhalation $LC_{50}$ Males > 5.6 mg/l**
**Estimated Inhalation $LC_{50}$ Females > 5.6mg/l**

Raid BD493 is assigned TOXICITY CATEGORY IV based on the LC50 in males and females.

This acute inhalation toxicity study is classified **acceptable** and satisfies the guideline requirement (§81-3) for an acute inhalation toxicity study.

**4) Primary Eye Irritation Study in Rabbits, MRID # 44186006**

CITATION: Glaza, Steven M. (1993): Primary Eye Irritation Study of Raid BD493 /n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) Dimethyl Benzyl Ammonium Chloride/n-Alkyl (68% C12, 32% C14) Dimethyl Ethylbenzyl Ammonium Chloride/3-(trimethoxysilyl) Propyl Dimethyl Octadecyl Ammonium Chloride [7217H121] in Rabbits. Hazleton Wisconsin, Inc. Laboratory Project I.D. HWI 21103440. MRID # 44186004. Unpublished.

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID # 44186006), adult HRA:(NZW)SPF strain rabbits (3/sex), received a single 0.1ml instillation of undiluted test material (Raid BD493) into the everted lower eyelid of the right eye. Eyes remained unflushed, and ocular irritation was recorded for up to 7 days post-treatment. The method of Draize was used for scoring. Eyes of all treated rabbits showed no ocular abnormalities by day 7 post-treatment. **In this study, Raid BD493 is considered a mild eye irritant and is placed in TOXICITY CATEGORY III** for primary eye irritation, based on corneal involvement which cleared in 7 days or less.

This primary eye irritation study is classified **acceptable** and satisfies the guideline requirement (§81-4) for a primary eye irritation study.

**5) Primary Dermal Irritation in Rabbits, MRID # 44186007**

CITATION: Glaza, Steven M. (1993): Primary Dermal Irritation Study of Raid BD493 /n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) Dimethyl Benzyl Ammonium Chloride/n-Alkyl (68% C12, 32% C14) Dimethyl Ethylbenzyl Ammonium Chloride/3-(trimethoxysilyl) Propyl Dimethyl Octadecyl Ammonium Chloride [7217H121] in Rabbits. Hazleton Wisconsin, Inc. Laboratory Project I.D. HWI 21103440. MRID # 44186007. Unpublished.

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID # 44186007), adult HRA:(NZW)SPF strain rabbits (3/sex), received a single 0.5ml dermal application of undiluted test material (Raid BD493) on the shaved back. Exposure time was 4 hours. Rabbits were observed for dermal irritation up to 7 days post-application. The method of Draize was used for scoring. Skin of all treated rabbits showed no dermal abnormalities by day 7 post-treatment. **In this study, Raid BD493 is considered a mild dermal irritant and is placed in TOXICITY CATEGORY IV** for primary dermal irritation, based on the presence of slight dermal irritation at 72 hours post-application.

This primary dermal irritation study is classified **acceptable** and satisfies the guideline requirement (§81-5) for a primary dermal irritation study.

**6) Dermal Sensitization in Guinea Pigs, MRID # 44186008**

CITATION: Glaza, Steven M. (1993): Dermal Sensitization Study of Raid BD493 /n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) Dimethyl Benzyl Ammonium Chloride/n-Alkyl (68% C12, 32% C14) Dimethyl Ethylbenzyl Ammonium Chloride/3-(trimethoxysilyl) Propyl Dimethyl Octadecyl Ammonium Chloride [7217H121] in Guinea Pigs - Closed Patch Technique. Hazleton Wisconsin, Inc. Laboratory Project I.D. HWI 21103442. MRID # 44186008. Unpublished.

EXECUTIVE SUMMARY: In a dermal sensitization study (MRID # 44186008), young adult albino guinea pigs of the Crl:(HA)BR strain were tested using the closed patch technique. Three induction phase applications of 0.4ml undiluted Raid BD493 were made to the shaved backs of 10 guinea pigs over a period of three weeks (1 application per week). Two weeks after the last induction dose, a challenge dose was applied in the same manner as the induction dose at a different site. Naive control guinea pigs were also treated at this time. Slight to moderate erythema reactions with pinpoint areas of subcutaneous hemorrhaging were observed in two of ten test animals after the third induction dose. After challenge application, no evidence of sensitization was observed in test animals or naive controls. Although positive control animals did not show evidence of sensitization (based on the degree of dermal reaction obtained during challenge), the test material itself was used undiluted, precluding the use of higher doses. Thus, the results of this study demonstrate that Raid BD493 is not a skin sensitizer, although more definitive positive control data would lend validity to the experimental procedure employed.

This dermal sensitization study is classified **acceptable** and satisfies the guideline requirement (§81-6) for a dermal sensitization study in guinea pigs.